

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
31-R-0010

CUSTOMER NO.
523

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

THE PROCTER & GAMBLE COMPANY
P.O. BOX 538707
CINCINNATI, OH 45253

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	31	185	105	4	294
5. Cats					
6. Guinea Pigs	19	21	182		203
7. Hamsters	1		9		9
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs	5		92		92
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)(c)

10/21/2005

Rw
gm

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 31-R-0010

2/3. Species (common name) & Number of animals used in this study:

Dogs (4)

4. Explain the procedure producing pain and/or distress.

These studies are used to determine the toxicity of novel pharmaceutical agents, aid in the selection of doses for future studies and describe the toxicokinetics of agents following repeated administration. The canine model used for these studies is a well established model for repeat dose toxicity testing with the FDA and equivalent international agencies. Results from these studies are used to assess the potential safety of new pharmaceuticals in future clinical studies. During the course of these studies 4 animals were identified as experiencing pain/distress related to drug compound.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

It is possible that some new test agents may result in signs of toxicity. The use of preventative analgesics at this phase of the study when potentially new pharmaceuticals are tested would interfere with the accurate evaluation of these new drug therapies. When and if animals do develop symptoms that are treatable, conditions are treated and/or dosing is discontinued.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: Not applicable.

CFR:

NOV 09 2005

Assurance Statement Federal Fiscal Year October 1, 2004 through September 30, 2005

We hereby certify that:

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by the research facility.
2. Each principal investigator has considered alternatives to painful procedures.
3. The facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC.

One exception to the standards was approved by the IACUC. A small group of dogs (<60) were part of a gingivitis colony. This model had been shown to be dependent on an oral microbial flora which is adversely affected by the use of disinfecting agents in the dog's primary enclosure. The IACUC approved an exception to the standards that require disinfection every two weeks. They did, however, require that dog runs be physically cleaned by washing twice daily with hot water and at the end of the study (4-6 weeks) with detergents and high-pressure water. This exception has not had any detectable adverse impact on the health status of the animals involved in the study or on the appearance of the facility. The study is no longer in progress and all kennels are now being disinfected every two weeks.

4. The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

(b)(6), (b)(7)c